

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY
PATENT LITIGATION

MDL No. 1592 (MLW)

This Document Relates To All Actions

**REPLY MEMORANDUM OF LAW IN SUPPORT OF COLUMBIA UNIVERSITY'S
MOTION TO STAY LITIGATION PENDING CONCLUSION OF
REEXAMINATION AND REISSUE PROCEEDINGS IN THE PATENT AND
TRADEMARK OFFICE**

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PRELIMINARY STATEMENT

Plaintiffs acknowledge that the '275 patent may emerge from reexamination or reissue proceedings with new or amended claims. Indeed, they concede that this is the most likely outcome. They nevertheless urge the Court to require Columbia to defend the validity of the '275 patent simultaneously in these five consolidated actions as well as before the Patent and Trademark Office ("PTO"). Plaintiffs' proposal virtually guarantees that the parties will spend millions of dollars litigating the validity of a patent that will be surrendered and reissued with new and amended claims. The likelihood of this outcome is all the more apparent from Columbia's reissue application, which is being filed with the PTO on June 18, 2004, and which amends several of the existing claims and seeks issuance of a number of new claims. Relevant parts are attached as Exhibits 6 and 7.¹

Plaintiffs present no compelling reason for this Court to part company with the many decisions that have recognized the important role of reexamination and reissue and the necessity of staying costly litigation until the conclusion of those proceedings. Plaintiffs' argument that Columbia has improperly sought to delay the resolution of these cases is nothing more than a smokescreen for their own Herculean efforts to stymie Columbia's attempt to achieve consolidation of these virtually identical actions in a single forum. Having lost that battle, plaintiffs would now have this Court fragment Columbia's defense of the '275 patent into two different arenas. That effort, too, should be rejected.

¹ Unless otherwise noted, the accompanying Supplemental Declaration of David I. Gindler contains the exhibits cited in this Memorandum.

ARGUMENT

A. Columbia Has Neither Sought A Stay For Purposes Of Delay Nor Improperly Attempted To Delay The Resolution Of These Actions

A review of the caselaw reveals that a stay of litigation pending the outcome of reexamination or reissue proceedings is ordinarily granted when a case “is in its incipient stages” and “[t]he parties have not engaged in expensive discovery and no trial date has been set.” *Guthy-Renker Fitness L.L.C. v. Icon Health and Fitness Inc.*, 48 U.S.P.Q.2d 1058, 1060 (C.D. Cal. 1998). In an effort to overcome this well established principle of judicial economy, plaintiffs argue that Columbia is using the reexamination process as a tactical device solely for purposes of delay. Nothing could be further from the truth.

The reexamination petition was filed by a third party, Public Patent Foundation (“PubPat”), without any prior notice to or consultation with either Columbia or any of the plaintiffs. Columbia did not seek or desire reexamination of the ’275 patent. When the plaintiffs filed their actions challenging the validity and enforceability of the ’275 patent, Columbia was content to defend these actions in the courts, without any involvement from the PTO. As a result, unlike many other patent-holders facing a challenge to the validity of their patents, Columbia did nothing to seek review of the ’275 patent in the PTO and thereby achieve a delay in the litigation. Columbia was confident then—and remains confident today—that all challenges to the validity and enforceability of the ’275 patent ultimately will fail.

The landscape of this litigation fundamentally changed on May 6, 2004, when the PTO granted PubPat’s request for reexamination. Mot. to Stay, Ex. B. At that point, all parties needed to consider carefully whether it made sense to litigate the same validity issues simultaneously in two separate forums or to stay these consolidated actions pending the

outcome of reexamination proceedings. Columbia concluded—as have the vast majority of federal courts confronting the issue at the early stages of a case—that a stay of the litigation was highly preferable to devoting millions of dollars to defend the validity of patent claims that may be cancelled or amended by the PTO. Moreover, Columbia also concluded that, since the PTO had decided to reexamine the '275 patent, it would be beneficial to invoke a related PTO procedure—reissue—to address certain errors it had identified in some of the claims in the '275 patent and to secure the full scope of patent protection to which it is entitled. Columbia did not file a reissue application until after the granting of the request for reexamination because, in the absence of the PTO's decision to reexamine the '275 patent, Columbia was prepared to live with certain imperfections in the claim language of and protection afforded by the patent in its present form.

Plaintiffs also accuse Columbia of attempting to delay their cases from the very outset of the litigation. Again, nothing could be further from the truth. Quite to the contrary, plaintiffs have done everything in their power to make this litigation onerous, inefficient, and unfair to Columbia. Between April 2003 and November 2003, twelve pharmaceutical companies filed seven essentially identical actions in four different judicial districts. As one after another of these actions was filed over a period of seven months, Columbia immediately identified the need to transfer all of the cases to a single forum for consolidated proceedings. Accordingly, Columbia first attempted to achieve this goal by filing motions to transfer under 28 U.S.C. § 1404(a) in the interests of justice and for the convenience of the parties and witnesses. The advantage of moving under 28 U.S.C. § 1404(a) instead of 28 U.S.C. § 1407(a) is that the former provides for transfer and consolidation of both pre-trial and trial proceedings whereas the latter provides for transfer

and consolidation of only pre-trial matters. It is for that reason—and that reason alone—that Columbia stated in its motions to transfer under Section 1404(a) that recourse to the multidistrict litigation statute was not the preferred course.

Plaintiffs in the cases Columbia sought to transfer opposed these motions, preferring instead to pursue each case on a separate but simultaneous track, thereby allowing them to conduct duplicative discovery—including repetitive depositions of the same witnesses—and ultimately have multiple bites at the same validity apple. When the court in the *Amgen* case (then pending in Los Angeles) denied one of Columbia's motions under Section 1404(a) in a one-page order, Ex. 1, it then became impossible for Columbia to achieve its goal of transferring and consolidating all of the cases in a single judicial district for all purposes. As a result, Columbia pursued the next-best option: transfer and consolidation for pre-trial purposes only under Section 1407(a), the multidistrict litigation statute. True to form, every plaintiff opposed that motion as well. Indeed, in their oppositions to Columbia's motion, none of the plaintiffs even offered to participate in informal coordination of all discovery across all cases as an alternative to transfer under Section 1407(a). Faced with multiple cases presenting the same challenges to the validity and enforceability of the same patent, the Judicial Panel on Multidistrict Litigation granted Columbia's motion on April 8, 2004, Ex. 5, thereby putting to an end plaintiffs' efforts to fragment the litigation among multiple forums.

It is true that Columbia has resisted plaintiffs' efforts to multiply the burden and expense of this litigation by conducting discovery and other proceedings separately in each of their actions. Thus, Columbia has objected to Genentech's efforts to proceed with depositions without coordination among all of the cases, as well as Amgen's efforts to

pursue discovery on its own separate track. Yet on the occasions in which judicial intervention was required to stop plaintiffs from pursuing discovery on a piecemeal basis, Columbia's position was upheld. Exs. 3-5. If plaintiffs had cooperated in the least bit with Columbia's efforts to bring order and rationality to this process, the cases would be in a much different procedural posture today. Instead, plaintiffs have spent the last year skirmishing with Columbia in an effort to prevent coordination of discovery and other proceedings across all of their cases. Those efforts having failed, plaintiffs can only blame themselves for the resulting delay.

B. A Stay Will Avoid Wasteful and Duplicative Proceedings Before This Court

Plaintiffs do no dispute that the interpretation of the claims of the '275 patent is a fundamental issue in the case. Nor do they dispute that the claims of the '275 patent may be amended during the reexamination and reissue proceedings before the PTO. Accordingly, unless this action is stayed, the parties and the Court may expend needless time and effort addressing the interpretation of claims that will no longer exist in their present form after the conclusion of proceedings in the PTO.

Plaintiffs do not directly address this compelling reason to stay this multidistrict litigation. Nor do they deny that the PTO could invalidate all of the claims of the '275 patent, making all proceedings before this Court a terrible waste of time and money. Instead, plaintiffs argue that the Court should deny the motion to stay because they will prevail at a summary judgment hearing that may take place in mid-2005, which may or may not be before the PTO concludes reexamination and reissue proceedings. Plaintiffs cite no authority for the proposition that, when ruling on a motion to stay, a court should consider the non-movants' self-serving assumption that they will invalidate all claims of the subject patent at an early stage in the case—an assumption with which Columbia strongly disagrees.

Indeed, the principal circumstance in which courts take into account the relative pace of court proceedings versus PTO proceedings is when a motion to stay has been filed after discovery is essentially complete or the case is set for trial. *Perricone v. Unimed Nutritional Services, Inc.*, No. Civ.A. 301CV512(CFD), 2002 WL 31075868, at *3 (D. Conn. July 18, 2002) (“Most often, a request for a stay has been denied due to the late stage of litigation, the fact that discovery was or would be almost completed, or trial had been set.”). These consolidated actions, of course, are still in their infancy.

In any event, ignoring plaintiffs’ representations as to which side has the better case, and given the complexity of issues and number of parties in these five consolidated actions, it is hard to imagine that there will be any meaningful difference between the relative speed of proceedings in this Court or before the PTO. Moreover, even in the unlikely event that plaintiffs prevail on summary judgment in mid-2005, that judgment would not bring the validity challenge to the ’275 patent to an end. Rather, there would still be a lengthy appeal to the Federal Circuit and the possibility of reversal.² And, although plaintiffs suggest otherwise, Joint Mem. Opp. at 9, the PTO will not cease reexamination of the ’275 patent upon entry of a judgment of invalidity by this Court. Rather, reexamination will continue until there has been a ruling from the Federal Circuit upholding a judgment of invalidity of

² Given that plaintiffs’ invalidity theories turn upon the interpretation of the claims of the ’275 patent, there is a very real possibility that the Federal Circuit will reverse any judgment in this case, no matter which side ultimately prevails. This is because the Federal Circuit conducts a *de novo* review of every claim construction ruling, *W.E. Hall Co., Inc. v. Atlanta Corrugating, LLC*, No. 03-1417, 2004 WL 1237608, at *5 (Fed. Cir. June 7, 2004), and the reversal rate on claim construction is very high. Nearly a third of claim construction rulings are reversed on appeal. See Chris Ullsperger, *Lessons in Claim Construction from the Federal Circuit*, Intellectual Property Today, Sept., 2002, at 14. Ex. 8.

the particular claims under reexamination.³ At that point, although reexamination will cease as to the particular claims held invalid or unenforceable on appeal, “the reexamination will continue if any original, new, or amended claim was not found invalid or unenforceable by the Court.” Manual of Patent Examining Procedure § 2286, at 2200-127 (8th ed., May 2004 Rev.)⁴ (“MPEP”) (Ex. 11). Accordingly, even if plaintiffs were to prevail on summary judgment, the ’275 patent could emerge from reexamination with new or amended claims either before or after the appeal has concluded—thereby mooted the entire appeal, not to mention all of the time and effort expended litigating the case before this Court.

In addition, there is no PTO procedure requiring termination of reissue proceedings based upon a trial court judgment or a Federal Circuit decision finding the ’275 patent to be invalid. Rather, Columbia simply has a continuing duty to inform the examiner of relevant events concerning the litigation. MPEP § 1442.04. Ex. 9. The Federal Circuit has recognized that the question of the validity of a reissue patent is distinct from, and not necessarily determined by, the validity of the original patent. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1137, 1141 (Fed. Cir. 1985) (“When a patent has been reissued with claims that are not substantially identical to the original claims, the invention as a whole, as now claimed, must be evaluated in terms of [one of the standard requirements for validity]. The original claims, whether valid or invalid, are not prior art against the reissued

³ Manual of Patent Examining Procedure § 2286, at 2200-127 (8th ed., May 2004 Rev.) (“MPEP”) (“On the other hand, a *final* Federal Court holding of invalidity or unenforceability (after all appeals), is binding on the Office. Upon the issuance of a final holding of invalidity or unenforceability, the claims held invalid or unenforceable will be withdrawn from consideration in the reexamination.”) (emphasis in original) (Ex. 11).

⁴ The PTO recently released a new revision of the MPEP. Columbia has attached the relevant portions as exhibits. The Court can access the new revision of the MPEP at www.uspto.gov.

claims....Having determined that a reissue claim is not substantially identical to the parent, the parent claim is of no further moment.”); *Antonious v. Wilson Sporting Goods Co.*, No. 89 C 6675, 1990 WL 186582, at *4 (N.D. Ill. Nov. 16, 1990) (patent owner was “not barred from bringing claims under a reissue patent although the parent patent had been previously held invalid” because “a reissued patent presents a different claim than the parent patent.”).

Plaintiffs point out that, unless the PTO invalidates all claims of the '275 patent, the parties will need to return to this Court to litigate the validity and enforceability of whatever claims of the patent emerge from reexamination or reissue proceedings. That is certainly true, but it is hardly a reason to deny Columbia's motion to stay. Quite to the contrary, the very purpose of a stay is to allow the parties and the Court to take into account the decision of the PTO after reexamination and reissue proceedings have been concluded. That is a sensible and pragmatic approach, for it avoids needless litigation over claims that may be cancelled or amended by the PTO. *See, e.g., Vitronics Corp. v. Conceptronic, Inc.*, 36 F. Supp. 2d 440, 442 (D.N.H. 1997) (“The reexamination process could more precisely define the scope of claim 1, or it could leave claim 1 unchanged. Because determining the scope of the disputed claim is central to the resolution of this case, it would be inefficient for the court to expend time and resources engaging in claim interpretation while the scope of the claim is still under review at the PTO.”); *Tap Pharmaceutical Products, Inc. v. Atrix Laboratories, Inc.*, No. 03 C 7822, 2004 WL 422697, at *2 (N.D. Ill. Mar. 3, 2004) (“There is a significant chance that the PTO will either invalidate this patent or drastically decrease its scope. This creates a very real possibility that the parties will waste their resources

litigating over issues that will ultimately be rendered moot by the PTO's findings."'). That approach should be followed here.⁵

C. Plaintiffs Will Not Suffer Any Prejudice Or Clear Tactical Disadvantage From The Granting Of A Stay

As established in Columbia's moving papers, plaintiffs will incur no increased financial liability to Columbia from the granting of a stay: If plaintiffs prevail, their royalty liability ceases as of the date on which they filed their respective actions (assuming that they stopped paying royalties by that date). On the other hand, if Columbia prevails, plaintiffs' exposure to the '275 patent will continue until 2019, irrespective of the date of the judgment. Accordingly, there is no basis for Wyeth to argue that, as a *quid quo pro* for the granting of a stay, Columbia should waive its right to recover infringement damages that would otherwise accrue, or to pursue infringement claims against products in development, during the period

⁵ Some of the plaintiffs argue that "courts generally deny stays" in declaratory relief actions. Joint Mem. Opp. at 17. This is simply untrue. *See, e.g., Implant Innovations, Inc. v. Nobelpharma AB*, No. 93-C-7489, 1994 WL 68498, at *3-4 (N.D. Ill. Feb. 25, 1994) (staying declaratory judgment action and rejecting argument that "stay puts a 'larger and larger cloud' over [3I's] head because it keeps accumulating potential damages"). None of the cases that plaintiffs cite contains any such statement or even remotely supports this conclusion. Two of the cases denied stay motions because considerable discovery had already occurred. *See Arctic Cat, Inc. v. Injection Research Specialists, Inc.*, No. Civ. 01-543 MJDRLE, 2003 WL 22047872, at *2 (D. Minn. Aug. 29, 2003) (case had been underway for nearly two years with "significant" exchange of discovery); *Enprotech Corp. v. Autotech Corp.*, No. 88 C 4853, 1990 WL 37217, at *1 (Mar. 16, 1990) ("[m]ost compelling" reason to deny stay was that discovery was "almost completed" and trial was less than two months away). A third case, *American Ceramicraft, Inc. v. Eisenbraun Reiss Inc.*, Civ. No. 92-2851, 1993 WL 498863, at *21 (D.N.J. June 16, 1993), had proceeded sufficiently to enable the court to enter summary adjudication on the plaintiffs' invalidity claims. The final cited case, *Yates-American Machine Co., Inc. v. Newman Machine Co., Inc.*, 694 F. Supp. 155, 158 (M.D.N.C. 1988), involved a decision not to stay a challenge to three patents where only one of them was in a reissue proceeding.

of the stay. The granting of a stay is simply irrelevant to plaintiffs' exposure under the '275 patent.⁶

The principal argument advanced by all plaintiffs is that they would be prejudiced by a stay because their potential liability under the '275 patent may cause them to defer the development of future products or to raise the prices of existing products. This argument is outrageous and unsupportable hyperbole. Not one of the plaintiffs has attempted to support this argument with even the slightest bit of evidence. There are no witness affidavits, no manufacturing reports, no customer surveys, no expert analyses. Nor have plaintiffs offered any evidence that the royalties paid to Columbia in the past years for sales of products covered by the three previous Axel patents—on average, one percent of net sales of those products—caused them to increase prices or explore alternative manufacturing processes. It simply defies credulity to believe that a stay of this case will affect the development and delivery of pharmaceutical products from these multi-billion dollar companies. In short, lacking any basis to claim real prejudice from the granting of a stay, plaintiffs have invented one out of thin air.

⁶ In addition, contrary to plaintiffs' suggestions, their right to participate in the PTO is meaningful and substantial. Each plaintiff will be able to file a protest. MPEP § 1441.01, at 1400-48 (Ex. 10). In addition, plaintiffs can submit any evidence they want in support of their protests. MPEP § 1901.02, at 1900-2 ("Protests may be based on any facts or information adverse to patentability. The content and substance of the protest are more important than whether prior art documents, or some other form of evidence adverse to patentability, are being relied on.") (Ex. 10); § 1901.03, at 1900-4 (contemplating that a protester may file an "affidavit, or declaration") (Ex. 10). Given their numbers, plaintiffs should have ample opportunities to file all the protests necessary to apprise the PTO of the information they believe relevant.

Plaintiffs also weakly argue that delay itself is prejudicial because documents may be lost or memories may fade. If plaintiffs' argument were to be credited, then every motion to stay should be denied. Of course, that is not the law. Plaintiffs' speculation about what might occur during the duration of a stay is no substitute for real prejudice or clear tactical disadvantage when deciding whether to allow potentially wasteful and duplicative proceedings to proceed simultaneously in the both the courts and the PTO. There is no suggestion that any of the key witnesses in the case—the inventors, prosecuting attorneys, or Columbia administrators—is in ill health. The Court can always guard against such an eventuality by requiring Columbia to promptly report in the event that any significant witness develops a substantial health issue or otherwise might become unavailable during the period of the stay.

CONCLUSION

For the reasons set forth in the moving papers and in this reply, Columbia respectfully requests that this Court grant a stay of these all MDL proceedings pending the conclusion of reexamination and reissue proceedings.

Respectfully submitted,

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